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News / Story reproduced with thanks:- **Pharmabiz**

State FDA, CDSCO order Bharat Serum to stop production at Ambernath facility

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Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=55396§ionid=>

The state and central drug regulators have ordered the Bharat Serums and Vaccines Ltd, the vaccine manufacturing major in the country, to stop production in its manufacturing facility at Ambernath, Mumbai, following several irregularities found in the facility during a raid conducted by the state and central drug regulators.

The facility was raided by officers from FDA, Maharashtra and Central Drug Standard Control Organisation (CDSCO), West Zone on May 5 and 6, 2010, following a tip off from a newspaper report. According to the report, the company's animal farm at Khoni, which keeps horses for lab uses, has been violating Committee for the Purpose of Control and Supervision on Experiments on Animals (CPCSEA) in testing its anti-snake venom, anti-rabies serum and anti-thymocyte globulin products.

Though the company informed the regulators that it has stopped bleeding horses from March 16, 2010, the inspection team seized plasma secured even on May 3, 2010. Further, the team also identified that the plasma has been transferred from the animal farm at Khoni to the manufacturing facility at Ambernath without adhering to the cold chain management regulations.

The inspection team observed several major deficiencies and irregularities which are highly serious in nature, said a higher drug regulatory official. Considering the seriousness of the observations by the inspection team about the manufacturing premises where very sensitive and life saving drugs are produced, the Deputy Drugs Controller (I), CDSCO, West Zone and the Joint Commissioner (Konkan Division), FDA, Thane who is also the licensing authority, ordered the firm to stop production of the drugs licensed to manufactured under licences in Form 28-D(Licence No. KD-4), and Form 28-E (Lic. No KD-5) immediately in the interest of the public health at large, added that source.

A detailed show cause notice as to why the aforesaid licences should not be suspended or canceled is being issued to the firm shortly.

As per reports, the Khoni animal farm of Bharat Serums has been flouting CPCSEA regulations in not keeping horses as per norms and providing care for old or retired horses.